

§ 2000. PHARMACY BENEFIT MANAGEMENT

The commissioner may implement all or a portion of the pharmacy best practices and cost control program through a contract with a third party with expertise in the management of pharmacy benefits.

§ 2001. LEGISLATIVE OVERSIGHT

(a) In connection with the pharmacy best practices and cost control program, the commissioner of prevention, assistance, transition, and health access shall report for review by the health access oversight committee, prior to initial implementation, and prior to any subsequent modifications:

(1) the compilation that constitutes the preferred drug list or list of drugs subject to prior authorization or any other utilization review procedures;

(2) any utilization review procedures, including any prior authorization procedures; and

(3) the procedures by which drugs will be identified as preferred on the preferred drug list, and the procedures by which drugs will be selected for prior authorization or any other utilization review procedure.

(b) The health access oversight committee shall closely monitor implementation of the preferred drug list and utilization review procedures to ensure that the consumer protection standards enacted pursuant to section 1999 of this title are not diminished as a result of implementing the preferred drug list and the utilization review procedures, including any unnecessary delay in access to appropriate medications. The committee shall ensure that all affected

interests, including consumers, health care providers, pharmacists and others with pharmaceutical expertise have an opportunity to comment on the preferred drug list and procedures reviewed under this subsection.

(c) The commissioner of prevention, assistance, transition, and health access shall report quarterly to the health access oversight committee concerning the following aspects of the pharmacy best practices and cost control program:

(1) the efforts undertaken to educate health care providers about the preferred drug list and the program's utilization review procedures;

(2) the number of prior authorization requests made; and

(3) the number of utilization review events (other than prior authorization requests).

(d) On or before January 1, 2003, and on or before January 1 of each year for the duration of the pharmacy benefit manager contract, the commissioner of prevention, assistance, transition, and health access shall report to the house and senate committees on health and welfare, and to the health access oversight committee, concerning implementation of any pharmacy benefit manager contract entered into by the pharmacy best practices and cost control program. The report shall include:

(1) a description of the activities of the pharmacy benefit manager;

(2) an analysis of the success of the pharmacy benefit manager in achieving each of the department's public policy goals, together with the pharmacy benefit manager's report of its activities and achievements;

(3) an assessment of Medicaid and VScript program administrative costs relating to prescription drug benefits, including any recommendations for increasing the administrative efficiency of such programs;

(4) a fiscal report on the state fiscal costs and savings to Vermont of the pharmacy benefit manager contract, including an accounting of any payments, fees, offsets, savings and other financial transactions or accountings;

(5) any recommendations for enhancing the benefits of the pharmacy benefit manager contract, and an identification of, and any recommendations for minimizing any problems with the contract; and

(6) if the department has not entered into a contract with a pharmacy benefit manager, or if any such contract has been rescinded, any recommendations for pursuing Vermont's public policy goals relating to pharmaceutical costs, quality and access through other means.

(e)(1) The fiscal report required by subdivision (d)(4) of this section shall include the disclosure, in a manner that preserves the confidentiality of any proprietary information as determined by the commissioner, of:

(A) any agreements entered into by the pharmacy benefit manager identified in subdivision (2) of this subsection; and

(B) the financial impact of such agreements on Vermont, and on Vermont beneficiaries.

(2) The commissioner shall not enter into a contract with a pharmacy benefit manager unless the pharmacy benefit manager has agreed to disclose to the commissioner the terms and the financial impact on Vermont and on Vermont beneficiaries of:

(A) any agreement with a pharmaceutical manufacturer to favor the manufacturer's products over a competitor's products, or to place the manufacturer's drug on the pharmacy benefit manager's preferred list or formulary, or to switch the drug prescribed by the patient's health care provider with a drug agreed to by the pharmacy benefit manager and the manufacturer;

(B) any agreement with a pharmaceutical manufacturer to share manufacturer rebates and discounts with the pharmacy benefit manager, or to pay "soft money" or other economic benefits to the pharmacy benefit manager;

(C) any agreement or practice to bill Vermont health benefit plans for prescription drugs at a cost higher than the pharmacy benefit manager pays the pharmacy;

(D) any agreement to share revenue with a mail order or internet pharmacy company;

(E) any agreement to sell prescription drug data concerning Vermont beneficiaries, or data concerning the prescribing practices of the health care providers of Vermont beneficiaries; or

(F) any other agreement of the pharmacy benefit manager with a pharmaceutical manufacturer, or with wholesale and retail pharmacies, affecting the cost of pharmacy benefits provided to Vermont beneficiaries.

(3) The commissioner shall not enter into a contract with a pharmacy benefit manager who has entered into an agreement or engaged in a practice described in subdivision (2) of this subsection, unless the commissioner determines, and certifies in the fiscal report required by subdivision (d)(4) of this section, that such agreement or practice furthers the financial interests of Vermont, and does not adversely affect the medical interests of Vermont beneficiaries.

§ 2002. SUPPLEMENTAL REBATES

(a) The commissioner, separately or in concert with the authorized representatives of any participating health benefit plan, shall use the preferred drug list authorized by the pharmacy best practices and cost control program to negotiate with pharmaceutical companies for the payment to the commissioner of supplemental rebates or price discounts for Medicaid and for any other state public assistance health benefit plans designated by the commissioner, in addition to those required by Title XIX of the Social Security Act. The commissioner may also use the preferred drug list to negotiate for the payment

of rebates or price discounts in connection with drugs covered under any other participating health benefit plan within or outside this state, provided that such negotiations and any subsequent agreement shall comply with the provisions of 42 U.S.C. § 1396r-8. The program, or such portions of the program as the commissioner shall designate, shall constitute a state pharmaceutical assistance program under 42 U.S.C. § 1396r-8(c)(1)(C).

(b) The commissioner shall negotiate supplemental rebates, price discounts, and other mechanisms to reduce net prescription drug costs by means of any negotiation strategy which the commissioner determines will result in the maximum economic benefit to the program and to consumers in this state, while maintaining access to high quality prescription drug therapies. The provisions of this subsection do not authorize agreements with pharmaceutical manufacturers whereby financial support for medical services covered by the Medicaid program is accepted as consideration for placement of one or more prescription drugs on the preferred drug list. The January 1, 2003 report of the commissioner pursuant to subsection 2001(d) of this title shall include a cost-benefit analysis of alternative negotiation strategies, including the strategy used by the State of Florida to secure supplemental rebates, the strategy used by the State of Michigan to secure supplemental rebates, and any other alternative negotiation strategy that might secure lower net prescription drug costs.

(c) The commissioner and the department shall prohibit the public disclosure of information revealing company-identifiable trade secrets (including rebate and supplemental rebate amounts, and manufacturer's pricing) obtained by the department, and by any officer, employee or contractor of the department in the course of negotiations conducted pursuant to this section. Such confidential information shall be exempt from public disclosure under subchapter 3 of chapter 5 of Title 1 (open records law).

§ 2003. PHARMACY DISCOUNT PLAN

(a) On or before July 1, 2002, the commissioner shall implement a pharmacy discount plan, to be known as the "Healthy Vermonters" program, for Vermonters without adequate coverage for prescription drugs. The provisions of section 1992 of this title shall apply to the commissioner's authority to administer the pharmacy discount plan established by this section. The commissioner may establish an enrollment fee in such amount as is necessary to support the administrative costs of the plan.

(b) The pharmacy discount plan authorized by this section shall include a program implemented as a Section 1115 Medicaid waiver, wherein the state makes a payment toward the cost of the drugs dispensed to individuals enrolled in this program of at least two percent of the cost of each prescription or refill, consistent with the appropriation for the program established by this section.

(c) The commissioner shall implement the pharmacy discount program authorized by this section without any financial contribution by the state

otherwise required by subsection (b) of this section, and without federal waiver approval during such time as federal waiver approval has not been secured.

(d) As used in this section:

(1) "Eligible beneficiary" means any individual Vermont resident who is at least 65 years of age, or is disabled and is eligible for Medicare or Social Security disability benefits, with household income equal to or less than 400 percent of the federal poverty level, as calculated under the rules of the Vermont health access plan, as amended, and any other individual Vermont resident with household income equal to or less than 300 percent of the federal poverty level, as calculated under the rules of the Vermont health access plan, as amended; and

(2) "Vermonters without adequate coverage" includes eligible beneficiaries with no coverage for prescription drugs, and eligible beneficiaries whose annual maximum coverage limit under their health benefit plan has been reached.

§ 2005. PHARMACEUTICAL MARKETERS

(a)(1) Annually on or before January 1 of each year, every pharmaceutical manufacturing company shall disclose to the Vermont board of pharmacy the value, nature and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing home, pharmacist, health benefit plan

connection with a research study designed to answer specific questions about vaccines, new therapies or new ways of using known treatments;

(C) any gift, fee, payment, subsidy or other economic benefit the value of which is less than \$25.00; and

(D) scholarship or other support for medical students, residents and fellows to attend a significant educational, scientific or policy-making conference of a national, regional, or specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(b) The attorney general may bring an action in Washington superior court for injunctive relief, costs, and attorneys fees, and to impose on a pharmaceutical manufacturing company that fails to disclose as required by subsection (a) of this section a civil penalty of no more than \$10,000.00 per violation. Each unlawful failure to disclose shall constitute a separate violation.

(c) As used in this section:

(1) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in this state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include

administrator or any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state. Disclosure shall be made on a form and in a manner prescribed by the board. Initial disclosure shall be made on or before January 1, 2004 for the 12-month period ending June 30, 2003. The board shall provide to the office of the attorney general complete access to the information required to be disclosed under this subsection. The office of the attorney general shall report annually on the disclosures made under this section to the general assembly and the governor on or before March 1.

(2) Each company subject to the provisions of this section shall also disclose to the board, on or before October 1, 2002 and annually thereafter, the name and address of the individual responsible for the company's compliance with the provisions of this section.

(3) The Vermont board of pharmacy and the office of the attorney general shall keep confidential all trade secret information, as defined by subdivision 317(b)(9) of Title 1. The disclosure form prescribed by the board shall permit the company to identify any information that is a trade secret.

(4) The following shall be exempt from disclosure:

(A) free samples of prescription drugs intended to be distributed to patients;

(B) the payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials. As used in this subdivision, "clinical trial" means an approved clinical trial conducted in

committee on committees, which may include a member of the committee on committees, to serve as the Vermont directors of the Northeast Legislative Association on Prescription Drug Pricing. Directors so appointed from each body shall not all be from the same party. Directors so appointed shall serve until new members are appointed.

(c) For meetings of the Association, directors who are legislators shall be entitled to per diem compensation and reimbursement of expenses in accordance with section 406 of Title 2. If the lieutenant governor is appointed as a director pursuant to subsection (b) of this section, his or her compensation and expenses shall be paid from the appropriation made to the office of the lieutenant governor.

(d) The Vermont directors of the Association shall report to the general assembly on or before January 1 of each year with a summary of the activities of the Association, and any findings and recommendations for making prescription drugs more affordable and accessible to Vermonters.

Sec. 2. SECTION 1115 WAIVER FOR PHARMACEUTICAL PROGRAMS

(a) The commissioner shall request a Section 1115 waiver or waiver amendment in order to maximize federal financial participation in Vermont's state pharmaceutical assistance programs, and in order to preserve Vermonters' continued access to such programs, unless the commissioner determines that such waiver or waiver amendment will not provide a financial benefit to the state of Vermont over the long term. The commissioner shall report to the

a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.

(2) "Pharmaceutical manufacturing company" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a wholesale drug distributor or pharmacist licensed under chapter 36 of Title 26.

§ 2006. NORTHEAST LEGISLATIVE ASSOCIATION ON

PRESCRIPTION DRUGS PRICING

(a) The general assembly finds that the Northeast Legislative Association on Prescription Drug Pricing is a nonprofit organization of legislators formed for the purpose of making prescription drugs more affordable and accessible to citizens of the member states. The general assembly further finds that the activities of the Association provide a public benefit to the people of the state of Vermont.

(b) On or before January 15, upon the convening of each biennial session of the general assembly, three directors shall be appointed by the speaker, which may include the speaker, and three directors shall be appointed by the

health access oversight committee if she determines not to apply for such a waiver, or if she determines to apply for a waiver that is not consistent with the principles established in subsection (b) of this section in whole or in part.

(b) The waiver request shall conform to the following principles unless deviation is necessary to conduct successful negotiations with the Centers for Medicare and Medicaid Services:

(1) The waiver request shall propose a financially sustainable program designed to provide access to medically necessary prescription drugs for low income, elderly and disabled Vermonters.

(2) The waiver request shall propose to include all beneficiaries enrolled in the VScript-Expanded program (175 to 225 percent of the federal poverty level) in the Medicaid waiver population group.

(3) The waiver request shall consolidate and streamline program administration of and eligibility for Vermont's pharmaceutical assistance programs.

(4) The benefit plan and cost sharing provisions shall be designed to provide financial assistance and benefits based on the beneficiary's household income.

Sec. 2a. APPLICATION OF PREFERRED DRUG LIST TO NURSING

HOME PATIENTS

During fiscal year 2003, the preferred drug list of the department of prevention, assistance, transition and health access shall not apply to Medicaid

coverage of prescriptions for beneficiaries residing in a nursing home, including the Vermont Veterans' Home until the department proposes and the health access oversight committee approves a plan to notify and educate nursing home patients, their prescribers, and their pharmacy concerning the preferred drug list and the prior authorization process, and to ensure that Medicaid is securing the best price for cover drugs prescribed for nursing home residents. The department shall propose a plan to the committee by July 1, 2002.

Sec. 2b. 26 V.S.A. § 2032(c)(5) is added to read:

(c) The board of pharmacy shall also have the following responsibilities in regard to medications, drugs, devices and other materials used in this state in the diagnosis, mitigation and treatment or prevention of injury, illness, and disease:

* * *

(4) The issuance of certificates of registration and licenses of drug outlets;

(5) The development of criteria for a standardized tamper-resistant prescription pad that can be used by all health care providers who prescribe drugs. Such criteria shall be developed in consultation with pharmacists, hospitals, nursing homes, physicians and other prescribers, and other affected parties.

Sec. 3 [DELETED.]

Sec. 4. REPEAL

Subsections 123(n), (o), (p) and (q) of No. 63 of the Acts of 2001 are repealed.

Sec. 5. EFFECTIVE DATE

This act shall take effect on passage, except that:

(1) Sec. 1, 33 V.S.A. § 1999 (consumer protection rules), shall take effect 60 days after passage; and

(2) Sec. 1, 33 V.S.A. § 1999(d) (prior authorization and drugs used to treat mental illness) shall be repealed on July 1, 2004.

Sec. 6. OUTCOMES BASED ASSESSMENT AND TREATMENT

(a) Vermont's health care policies shall promote outcomes based assessment and treatment through the development of a statewide quality assurance system and an effective quality improvement process that integrates best practices research, functional status assessment, patient satisfaction measurements and cost containment goals. These health care policies are best established and implemented by nongovernmental organizations of health care providers and patients. The role of government should be to support efforts of nongovernmental organizations to remain collaborative in nature, and to recognize those efforts.

(b) Statewide quality assurance inventory. The commissioner of banking, insurance, securities and health care administration shall contract, subject to the availability of grants from federal government agencies and

nongovernmental organizations to support the costs of the contract authorized by this subsection, with a qualified nongovernmental organization to conduct an inventory of existing quality assurance measurements used by public and private health plans in Vermont, by hospitals serving Vermont residents, and by other entities within state government. The commissioner's contractor shall report to the commissioner with the results of the inventory, and with an analysis and identification of any other information necessary to establish a statewide quality assurance system.

(c) Evaluation of inventory.

(1) The commissioner of banking, insurance, securities and health care administration and the secretary of human services shall convene a work group to evaluate the results of the inventory, identify common areas of measurements to all, areas lacking measurements, and an analysis of likely areas for change in order to develop a statewide application of a quality assurance measurement. Additionally the work group may make proposals to the General Assembly for continued outcomes based assessments which may identify areas of health care which need improvement, provide for a comparison of the quality of health care provided under public and private health benefit plans, identify ways to focus resources and programs in order to improve the health of beneficiary populations or discrete portions thereof, and develop any other findings and recommendations for expanding access to,

improving the quality of, and lowering the cost of Vermont's health care system.

(2) The work group shall include representatives from private and public health plans, the Vermont Program for Quality in Health Care, Inc., the Vermont Association of Hospitals and Health Systems, the Dartmouth-Hitchcock Medical Center, the Vermont Medical Society, the University of Vermont medical school, the Vermont Child Health Improvement Project, the Area Health Educational Centers, and anyone else deemed appropriate by the commissioner and the secretary.

(d) Report to the General Assembly. The commissioner and the secretary shall make a joint report to the General Assembly on or before December 15, 2002 with findings and recommendations. The report shall include a summary of the activities of the commissioner and the secretary, and a description of any proposals to implementing outcomes based assessment projects.

Approved: June 13, 2002

Ryan, Robin

From: Ryan, Robin
Sent: February 27, 2003 2:09 PM
To: Sweet, Richard
Cc: Wischnewski, Marne; de Felice, David Patrick
Subject: PDL bill

If DHFS chooses to refer doctors to the medical examining board for prescribing drugs that are not on PDL, what should the investigation and sanction procedure be? Should it be like the procedures that the board uses under s. 448.02 for investigating and disciplining negligence and professional misconduct? Under s. 448.02 the board may warn or reprimand a person, or limit, suspend or revoke the person's license. Does prescribing off the PDL rise to the level of "professional misconduct?"

Or, should the investigation and sanction be outside the 448.02 process. For example, under s. 448.09 (1), the board may fine persons who over-charge patients for tests done by the state lab of hygiene.

Dick suggests just a fine

Ryan, Robin

From: de Felice, David Patrick
Sent: February 27, 2003 5:07 PM
To: Ryan, Robin
Subject: RE:

Robin,

I tried to respond to each of your points below.

David de Felice
Office of Rep. G. Spencer Coggs
State Assembly
608-266-5580 phone
608-282-3617 fax

-----Original Message-----

From: Ryan, Robin
Sent: Thursday, February 27, 2003 10:53 AM
To: Sweet, Richard
Cc: Wischnewski, Marne; de Felice, David Patrick
Subject: RE:

What is the relationship between the prescription drug card program for the uninsured (modeled after 2001 AB 857) and the preferred drug list.

[de Felice, David Patrick: Actually - you or others in our drafting group may have a different reading on this - I envision all participants in the program as having some kind of card to verify to pharmacists that they are a member of the PDL group.]

Presumably any rebate that a manufacturer agrees to in order to have its drug placed on the PDL would be applied to the cost of drugs purchased by persons who enroll in the prescription drug card program.

[de Felice, David Patrick: That is my understanding. The rebate will be applied across the entire membership of those receiving reduced cost drugs under the PDL.]

Beyond that is there any formal relationship between the PDL and the card program?

[de Felice, David Patrick: I'm not sure I understand this question other than to say that there should be nothing that distinguishes an un-insured person from, say, a state employee if they're both covered by the PDL. In other words two people walk into a pharmacy, one a state employee, the other an uninsured person eligible for the PDL program, they both present a card. They look exactly the same to the pharmacist, and they receive the same benefit.]

Should the existence of the PDL affect the prescribing habits of doctors who prescribe drugs for persons in the card program?

[de Felice, David Patrick: Absolutely. Physicians prescribing for PDL patients should give first preference to drugs on the PDL.]

Since the state isn't paying for drugs purchased under the card program there won't be any prior authorization requirement for drugs that aren't on the PDL.

[de Felice, David Patrick: I would think there would be prior authorization.] David: have DHFS grant PA

Should doctors who prescribe off-list drugs to persons in the card without medical justification be penalized in the same way they may be if they prescribe off-list drugs for Medical Assistance recipients?

[de Felice, David Patrick: I would think yes.]

-----Original Message-----

From: Sweet, Richard
Sent: February 25, 2003 4:57 PM
To: Ryan, Robin
Cc: Wischnewski, Marne; de Felice, David Patrick
Subject:

Ryan, Robin

From: de Felice, David Patrick
Sent: February 28, 2003 4:50 PM
To: Ryan, Robin
Subject: RE: PDL bill

Robin,

It appears that the less harsh sanctions (fines) as a first threshold, first offense, action might be more appropriate. We don't want the "death penalty" for first-time offenders. However, this is Rep. Underheim's area of expertise, so Rep. Coggs would defer to him.

Thanks,

David de Felice
Office of Rep. G. Spencer Coggs
State Assembly
608-266-5580 phone
608-282-3617 fax

-----Original Message-----

From: Ryan, Robin
Sent: Thursday, February 27, 2003 2:09 PM
To: Sweet, Richard
Cc: Wischniewski, Marne; de Felice, David Patrick
Subject: PDL bill

If DHFS chooses to refer doctors to the medical examining board for prescribing drugs that are not on PDL, what should the investigation and sanction procedure be? Should it be like the procedures that the board uses under s. 448.02 for investigating and disciplining negligence and professional misconduct? Under s. 448.02 the board may warn or reprimand a person, or limit, suspend or revoke the person's license. Does prescribing off the PDL rise to the level of "professional misconduct?"

Or, should the investigation and sanction be outside the 448.02 process. For example, under s. 448.09 (1), the board may fine persons who over-charge patients for tests done by the state lab of hygiene.

Ryan, Robin

From: Sweet, Richard
Sent: March 03, 2003 10:04 AM
To: Ryan, Robin; Wischnewski, Marne; de Felice, David Patrick
Subject: RE: PDL

Senate Bill 44 makes it mandatory for all public employers (state and local) starting on 1/1/05. This is a policy decision for Gregg and Spencer. It seems like a trade-off between the ability of public employees to bargain for something and a larger market share under the PDL.

Dick

-----Original Message-----

From: Ryan, Robin
Sent: Monday, March 03, 2003 9:25 AM
To: Wischnewski, Marne; de Felice, David Patrick; Sweet, Richard
Subject: PDL

Should state employees be required to use the PDL (see for example section 2063 of the governor's budget proposal) or should the PDL be a subject of collective bargaining as in the Vermont bill?

thanks

*D/c from Dave:
require collective bargaining*

I told Dave I didn't include local government in my question because there may be a home rule problem if require locals to participate.

Ryan, Robin

From: Sweet, Richard
Sent: March 04, 2003 3:57 PM
To: Ryan, Robin
Cc: Wischniewski, Marne; de Felice, David Patrick
Subject: PDL draft

Robin:

Reps. Coggs and Underheim have decided on the following with respect to the PDL draft:

- ✓ 1. Use of the PDL would be the subject of collective bargaining for public employers and employees.
- ~~no~~ ✓ 2. A provision would be added authorizing DHFS to buy prescription drugs from foreign sources (e.g. Canada).
- ~~mark~~ ✓ 3. The Vermont language on drugs company gifts to prescribers would be included.
- ✓ 4. The enrollment fee would be \$20, but DHFS would be required to review it after 1 year and reduce it if it provides revenues that are significantly in excess of program administrative costs.
- ✓ 5. Vermont language allowing businesses in would be included. Businesses would have to pay their share of administrative costs.

Marne and Dave, have I forgotten anything?

Thanks, Robin.

Dick Sweet
Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
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p/c to Dick

#2. Requesters want DHFS to buy drugs from Canada & get them to the pharmacists - i.e., act as distributor or wholesaler.

Ryan, Robin

From: Ryan, Robin
Sent: March 11, 2003 3:27 PM
To: Sweet, Richard; de Felice, David Patrick; Wischnewski, Marne
Subject: Can't import drugs from Canada

Federal law prohibits DHFS from importing prescription drugs. Under federal law, prescription drugs must be approved by the FDA to be marketed in the US -- regardless of whether they are originally manufactured in a foreign country or in the US. A 1987 federal law made it illegal for anyone other than the drug manufacturer to import a drug into the US.

In 2000, Congress passed legislation making it legal for pharmacists and wholesalers to import drugs from certain countries, including Canada. The legislation required the U.S. Dept. of Health and Human Services to set up a system for testing imported drugs for safety and for documenting the history of the drugs. The importation provision was contingent upon approval from the Secretary of the US Dept. of Health and Human Services -- specifically the Secretary had to find that the importation provision would not create a risk to public health, and would result in significant cost savings to consumers. In December of 2000, Secretary Shalala refused to approve the importation provision because she could not guarantee safety and cost savings. As far as I can tell, the Bush administration has not reversed Secretary Shalala's findings. The importation provision sunsets after 5 years, so it doesn't look like it will be implemented.

If you want further information on this you can look at this link to a Congressional Research Service report
<http://rxpolicy.com/studies/crs-106thimports-0101.pdf>

The 2000 importation provisions are in P.L. 106-387 (Section 745) codified at 21 USC 384.



State of Wisconsin
2003 - 2004 LEGISLATURE

LRB-1270/P1

RLR: /:....
WJ

Wanted by Thurs. 3/27 Am

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

D-Note

GEN

1 AN ACT ...; relating to: prescription drugs, providing penalties, and making
2 appropriations.

Analysis by the Legislative Reference Bureau

This is a preliminary draft. An analysis will be provided in a later version.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

3 SECTION 1. 20.005 (3) (schedule) of the statutes: at the appropriate place, insert
4 the following amounts for the purposes indicated:

	2003-04	2004-05
5		
6 20.435		
7 (4) HEALTH SERVICES PLANNING, REG. & DELIVERY, HLTH		
8 CARE FIN; OTHER SUPPORT PGMS		
9 (jg) Prescription drug assistance;		
10 enrollment fees	PR C -0-	-0-

			2003-04	2004-05
1	(jt) Preferred drug list	PR C	-0-	-0-
2	(jx) Supplemental rebates on pre-			
3	scription drugs; prescription			
4	drug assistance	PR C	-0-	-0-

5 SECTION 2. 20.435 (4) (jg) of the statutes is created to read:

6 20.435 (4) (jg) *Prescription drug assistance; enrollment fees*. All moneys
7 received from payment of enrollment fees under s. 49.692 (3), to be used for
8 administration of the program under s. 49.692.

9 SECTION 3. 20.435 (4) (jt) of the statutes is created to read:

10 20.435 (4) (jt) *Preferred drug list*. All moneys received from the payment of fees
11 under s. 49.69 (9), to be used for administration of the preferred drug list under s.
12 49.69.

13 SECTION 4. 20.435 (4) (jx) of the statutes is created to read:

14 20.435 (4) (jx) *Supplemental rebates on prescription drugs; prescription drug*
15 *assistance*. All moneys received from supplemental rebate payments by
16 manufacturers and labelers under s. 49.69 to provide Medical Assistance and Badger
17 Care benefits specified under s. 49.46 (2) (b) 6.h.; to pay pharmacies and pharmacists
18 under s. 49.688 (7) for prescription drug assistance for elderly persons; to assist
19 victims of disease, as provided in ss. 49.68, 49.683, and 49.685; to reimburse the cost
20 of drugs under s. 49.686; to pay a portion of the operating costs of the health
21 insurance risk-sharing plan under ch. 149; to purchase primary health care services
22 under s. 146.93; and to pay pharmacies and pharmacists under s. 49.692 (6) for

- ① prescription drug assistance. The amounts expended under this paragraph shall be
2 allocated as provided under s. 49.69 (7).[✓]

***NOTE: Where possible, this paragraph requires that rebate amounts be used to provide prescription drugs. Should I make the appropriation less restrictive, particularly with respect to Medical Assistance and Badger Care?

3 SECTION 5. 49.45 (49)[✓] of the statutes is repealed and recreated to read:

4 49.45 (49) PRESCRIPTION DRUG PRIOR AUTHORIZATION COMMITTEE. (a) The
5 secretary shall exercise his or her authority under s. 15.04 (1) (c)[✓] to create a
6 prescription drug prior authorization committee to do all of the following:

7 1. Advise the department on issues related to prior authorization decisions
8 made concerning prescription drugs on behalf of Medical Assistance recipients.

9 2. Determine the safety and clinical efficacy of prescription drugs for the
10 purpose of creating a preferred drug list as required under s. 49.69 (2).[✓]

11 (b) The secretary shall appoint as members of the prescription drug prior
12 authorization committee at least the following:

13 1. Two physicians, as defined in s. 448.01 (5)[✓], who are currently in practice.

14 2. Two pharmacists, as defined in s. 450.01 (15).[✓]

15 3. One advocate for recipients of Medical Assistance who has sufficient medical
16 background, as determined by the department, to evaluate the clinical efficacy of a
17 prescription drug.

18 4. For the purpose of making determinations under s. 49.69 (2)[✓] regarding the
19 safety and clinical efficacy of prescription drugs within a particular therapeutic
20 class, persons who have medical expertise with respect to the disease or medical
21 condition that the prescription drugs are intended to treat.

22 (c) A member of the prescription drug prior authorization committee may not
23 be employed by or be a party to a contract with the state, a manufacturer, as defined

Insert
3-3

1 in s. 450.01 (12),[✓] or a distributor, as defined in s. 450.01 (9),[✓] except that a person
2 whose only contract with the state is as a certified Medical Assistance provider under
3 ^{Sub.} ~~s. 49.45~~ (2) (a) 11.[✓] may be a member. Each committee member shall disclose any
4 potential conflicts of interest related to an issue on which the committee acts. A
5 member may not vote on an item if the member or the member's employer has a
6 conflict of interest in the outcome of the vote. A member who may not vote on an item
7 due to conflict of interest may participate in discussions related to the item.

****NOTE: This conflict of interest provision is from the Indiana bill. Is it too
restrictive, particularly with respect to the ban on state employees, for example doctors
who work at a state facility or at the university?

8 (d) Notwithstanding the requirement under s. 15.04 (1) (c)[✓] that members of
9 committees serve without compensation, members of the prescription drug prior
10 authorization committee who are not officers or employees of this state shall be paid
11 \$25 for each day on which they are actually and necessarily engaged in performance
12 of their duties, but not to exceed \$1,500 per year.

****NOTE: The request called for honorariums. This provision is modeled on a per
diem provision for board members under s. 15.07 (5), stats. Should the per diem amount
be different? Do you want to increase a DHFS appropriation to cover the cost of the per
diem? The per diem applies to the current activities of the committee as well as the added
responsibilities related to the preferred drug list.

13 (e) The prescription drug prior authorization committee shall accept
14 information or commentary from representatives of the pharmaceutical
15 manufacturing industry in the committee's review of prior authorization policies.

16 SECTION 6. 49.69[✓] of the statutes is created to read:

17 **49.69 Preferred drug list; prescription drug cost containment.** (1) In
18 this section:

19 (a) "Committee" means the prescription drug prior authorization committee
20 created under s. 49.45 (49).[✓]

(b) "Labeler" means a person that receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale, and has a labeler code issued by the federal food and drug administration under 21 CFR 207.20 (b).

(c) "Local governmental unit" means a political subdivision of this state, a special purpose district in this state, an instrumentality or corporation of the political subdivision or special purpose district or a combination or subunit of any of the foregoing.

(d) "Manufacturer" means a person engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs.

(e) "Off-list prescription drug" means a prescription drug that is not included on the preferred drug list created under sub. (5).[✓]

(f) "Practitioner" has the meaning given in s. 450.01 (17).[✓]

(g) "Prescription drug" has the meaning given in s. 450.01 (20).[✓]

****NOTE: This bill requires DHFS to consider all prescription drugs for the preferred drug list, not just those that are covered under the Medical Assistance program. ✱

(15) (h) "Single source prescription drug" means a prescription drug that is produced or distributed under an original new drug application approved by the federal food and drug administration under 21 USC 355.

(17) (i) "State-supported prescription drug program" means the Medical Assistance program or the program under s. 49.665[✓], 49.68[✓], 49.683[✓], 49.685[✓], 49.686[✓], 49.688[✓], or 146.93¹⁹ or ch. 149[✓].

(20) (j) "Therapeutic class" means a class of prescription drugs that are intended to treat the same disease or medical condition by substantially similar biochemical and physiological mechanisms.

1 (2) (a) By January 1, 2004, the committee shall classify prescription drugs by
2 therapeutic class. The committee may include a prescription drug in a therapeutic
3 class only upon finding that the prescription drug is safe and clinically effective in
4 treating the disease or medical condition that the therapeutic class is intended to
5 treat. The committee shall conduct an evidence-based analysis to determine the
6 safety and clinical efficacy of prescription drugs, including a review of relevant
7 literature. The committee shall periodically review and amend its classification of
8 prescription drugs.

9 (b) Notwithstanding par. (a), the committee may adopt safety and clinical
10 efficacy determinations made by a similar government entity in another state, if the
11 other entity uses standards for determining safety and clinical efficacy that are
12 similar to the standards used by the committee.

****NOTE: Should the committee be allowed to adopt determinations of clinical
efficacy and safety that are made by a private entity, such as a private health insurer?

13 (c) The committee shall make a determination regarding the safety and clinical
14 efficacy of a new single^o source prescription drug within 60 days after it is approved
15 by the federal food and drug administration or, if the committee does not receive
16 sufficient information to make a determination within 60 days after approval, within
17 60 days after receiving such information.

18 (3) (a) The department shall solicit bids or proposals from manufacturers and
19 labelers to provide rebates on prescription drugs that the committee has included in
20 therapeutic classes under sub. (2) and that are purchased under programs or plans
21 specified by the department.

22 (b) Any rebate offered by a manufacturer or labeler in response to a solicitation
23 under this subsection shall be in addition to any rebate that the manufacturer or

1 labeler provides for the prescription drug under 42 USC 1396r-8, if applicable, and
2 to any rebate required under state law or provided under an agreement between the
3 state and a manufacturer or labeler that is in effect on the effective date of this
4 paragraph [revisor inserts date].

***NOTE: According to Darcy, some manufacturers currently provide the MA rebate for drugs purchased under Senior Care and some do not. Will the requirement in this paragraph that proposed rebates ~~must~~ be supplemental to all current rebates put those manufacturers who currently provide rebates for Senior Care at a disadvantage compared to those who do not? Should this paragraph instead require that rebates be supplemental to the MA rebate, but not require that the rebates be supplemental to rebates under Senior Care and Disease Aids? How will DHFS determine the lowest cost drug in a therapeutic category if the cost of a drug after rebates is different for different programs? This paragraph does not specify that a manufacturer must offer the same supplemental rebate for each program covered in the DHFS solicitation, should it?

5 (c) The department may join with similar government entities in other states
6 to solicit rebates under this subsection.

7 (4) (a) The department may solicit bids or proposals under sub. (3) for rebates
8 on prescription drugs purchased under any of the following programs or plans:

- 9 1. State-supported prescription drug programs.
- 10 2. The prescription drug assistance program under s. 49.692.
- 11 3. Health care coverage plans offered by the state to state employees if use of
12 the preferred drug list is agreed to under collective bargaining.
- 13 4. Health care coverage plans offered by local governmental units to their
14 employees, if the local governmental units agree to use the preferred drug list.
- 15 5. Health care coverage plans offered by private entities to their employees, if
16 the private entities agree to use the preferred drug list.

17 (b) The department may initially solicit and secure rebates that apply to
18 prescription drugs purchased under one or more of the programs or plans under par.
19 (a) and may subsequently agree, in conjunction with manufacturers and labelers, to

1 apply the rebates to prescription drugs purchased under one or more of the
2 remaining programs or plans..

3 (5) (a) The department shall include the lowest-cost prescription drug in each
4 therapeutic class on a preferred drug list. The department may include one or more
5 additional prescription drugs within a therapeutic class on the preferred drug list,
6 if the cost of the drug is not significantly greater than the cost of the lowest-cost
7 prescription drug within the class.

8 (b) In determining cost under this subsection, the department shall consider
9 dosing practices, any cost reduction realized by the state as a result of rebate
10 agreements under 42 USC ^C1396r-8 or any other existing rebate agreement, any rebate
11 offered by a manufacturer under this section, and any other relevant cost
12 information.

13 (c) Notwithstanding pars. (a) and (b), the department shall include on the
14 preferred drug list all prescription drugs that the committee determines are safe and
15 clinically effective for treating acquired immunodeficiency syndrome or the human
16 immunodeficiency virus.

17 (6) By July 1, 2004, the department shall enter into agreements with
18 manufacturers and labelers to pay the ^ethe proposed rebates, if any, on prescription
19 drugs that are included on the preferred drug list created under sub. (5) and
20 purchased on or after July 1, 2004, under the programs and plans specified by the
21 department under sub. (3) (a). Rebates for prescription drugs purchased under
22 state-supported prescription drug programs or the prescription drug assistance
23 program under s. 49.962 shall be paid to the department.

****NOTE: Should the bill specify the length of rebate agreements or how frequently
the department must solicit new proposals?

(7) All rebates paid to the department under this section shall be credited to the appropriation account under s. 20.435 (4) (jx). The department shall calculate the amount of rebates earned on prescription drugs purchased under each of the state-supported prescription drug programs and under the program under s. 49.692, and shall allocate the amount earned under each program for that program.

****NOTE: The bill appropriates the rebates back into the programs under which they were earned—is this what you intend?

(8) The department shall implement at least one of the following prescription drug cost containment measures using the preferred drug list by July 1, 2004:

(a) The department may require practitioners to obtain prior authorization from the department or its fiscal agent for any off-list prescription drug purchased under a state-supported prescription drug program or under the program under s. 49.692 and may prohibit reimbursement of pharmacists, pharmacies, or any other provider for any off-list prescription drug purchased under a state-supported prescription drug program for which prior authorization is not obtained. If the department requires prior authorization under this paragraph, and a practitioner requests prior authorization for an off-list prescription drug, the department or its fiscal agent shall respond to the request by telephone or other telecommunication means within 24 hours after the request is received. In an emergency situation, the department shall reimburse a pharmacy or pharmacist for at least a 72-hour supply of a prescription without prior authorization.

****NOTE: Please consider how prohibiting reimbursement for off-list drugs will be implemented under the various state-supported prescription drug programs. Implementation seems fairly straightforward for Medical Assistance, Badger Care, and Senior Care, because DHFS pays the pharmacists. For HIRSP, will the state require that private insurers enforce use of the preferred drug list? Does the state pay pharmacists directly under the disease aids programs and Wisconcare? If not, how will this paragraph be enforced?

(b) The department may monitor the purchase of prescription drugs under state-supported prescription drug programs and ~~under~~⁹ the program under s. 49.692[✓] to identify practitioners who routinely prescribe off-list prescription drugs without medical justification and request that the medical examining board investigate and, if appropriate, sanction such practitioners under s. 448.075.[✓]

****NOTE: You may wish to reconsider requiring the department to implement a cost containment measure for the proposed prescription drug assistance program since the state does not pay for drugs under that program.

(9) The department shall encourage local governmental units and private entities that provide health insurance coverage to their employees to use the preferred drug list created under sub. (5)[✓] in their health insurance plans. The department shall assess a fee against local governmental units and private entities that agree to use the preferred drug list to fund a portion of the administrative costs of maintaining the preferred drug list. All fees paid to the department under this subsection[✓] shall be credited to the appropriation account under s. 20.435 (4) (jt).[✓]

****NOTE: The provisions in this bill relating to health insurance plans offered by private employers are directed at the employer rather than the insurance company. Is this what you intend?

(10) The department may enter into a contract with an entity to perform the duties and exercise the powers of the department under subs. (3)[✓] and (5).[✓]

SECTION 7. 49.692[✓] of the statutes is created to read:

49.692 Prescription drug assistance. (1) In this section:

(a) "Labeler" has the meaning given in s. 49.69 (1) (b).[✓]

(b) "Manufacturer" has the meaning given in s. 49.69 (1) (d).[✓]

(c) "Prescription drug" means a prescription drug, as defined in s. 450.01 (20),[✓] that is included as a benefit under s. 49.46 (2) (b) 6.h.[✓]

****NOTE: The prescription drug assistance program under this section covers only those prescription drugs that are covered as a Medical Assistance program benefit. The preferred drug list provision applies to all classes of prescription drugs (so that it can

serve the needs of government and private entity employees enrolled in health insurance plans that provide broader prescription drug coverage than Medical Assistance). Should the prescription drug assistance program cover all prescription drugs?

① (d) "Prescription order" has the meaning given in s. 450.01 (21).[↓]

2 (2) (a) A person to whom all of the following applies is eligible to purchase
3 prescription drugs for amounts established by the department under sub. (5):[↓]

4 1. The person is a resident, as defined in s. 27.01 (10) (a),[↓] of this state.

5 2. The person is not a recipient of Medical Assistance, does not have health care
6 coverage under s. 49.665,[↓] does not have a policy issued under ch. 149,[↓] and is not
7 enrolled in the program under s. 49.688.[↓]

8 3. The person has not had insurance coverage for prescription drugs for
9 outpatient care that is other than that specified in subd. 2,[↓] for at least 30 consecutive
10 days immediately before applying under par. (b),[↓] except that a person who receives
11 benefits under 42 USC 1395 to 1395ccc may have supplemental health insurance
12 that covers prescription drugs for outpatient care.

****NOTE: Will the eligibility provisions for this program encourage private insurers to drop coverage for prescription drugs?

13 (b) A person may apply to the department, on a form provided by the
14 department, for a determination of eligibility and issuance of a prescription drug
15 card for purchase of prescription drugs under this section.[↓]

16 (3) The department shall devise and distribute a form for applying for the
17 program under sub. (2),[↓] shall determine eligibility for each 12-month benefit period
18 of applicants, and, after payment by the applicant of a program enrollment fee for
19 each 12-month benefit period, shall issue to eligible persons a prescription drug card
20 for use in purchasing prescription drugs, as specified in sub. (4).[↓]

21 (4) Beginning, January 1, 2004, as a condition of participation by a pharmacy
22 or pharmacist in the program under ~~s.~~ 49.45,[↓] 49.46,[↓] or 49.47, the pharmacy or

1 pharmacist may not charge a person who presents a valid prescription order and a
2 card issued under sub. (3)[↓] an amount for a prescription drug under the order that
3 exceeds the maximum amount for the prescription drug established by the
4 department under sub. (5).[↓]

5 (5) (a) The department shall determine the maximum amount that a pharmacy
6 or pharmacist may, after December 31, 2003,[↓] charge a person who presents a card
7 issued under sub. (3)[↓] for a prescription drug. The amount may not be less than the
8 amount that the department reimburses a pharmacy or pharmacist for a
9 prescription drug under the Medical Assistance program plus the dispensing fee a
10 pharmacy or pharmacist may charge under the Medical Assistance program.

11 (b) Notwithstanding the maximum amount established by the department
12 under par. (a),[↓] a pharmacy or pharmacist may not, after December 31, 2003, charge
13 a person who presents a card issued under sub. (3)[↓] more than the usual and
14 customary charge of the pharmacy or pharmacist for a prescription drug plus the
15 dispensing fee a pharmacy or pharmacist may charge under the Medical Assistance
16 program.

17 (c) If the department secures an agreement from a manufacturer or labeler
18 under ^{5.} 49.69[↓] to provide a rebate on a prescription drug under this section, the
19 department shall reduce the amount that a pharmacy or pharmacist may charge for
20 the prescription drug by the amount of the rebate.

21 (d) The department shall calculate and transmit to pharmacies and
22 pharmacists that are certified providers of Medical Assistance amounts that may be
23 used in calculating charges under this subsection.[↓] The department shall periodically
24 update this information and transmit the updated amounts to pharmacies and
25 pharmacists.

1 (6) (a) If the department secures an agreement from a manufacturer or labeler
2 under ^{s.} 49.69[✓] to provide rebates on prescription drugs purchased by persons under
3 this section, the department shall do all of the following:

4 1. Devise and distribute a form for pharmacies and pharmacists to use to report
5 sales of prescription drugs to persons who have cards issued under sub. (3).[✓]

6 2. Collect from pharmacies and pharmacists utilization data necessary to
7 calculate the amounts to be reimbursed to the pharmacies and pharmacists under
8 this paragraph.[✓]

9 3. From the appropriation account under s. 20.435 (4) (jx),[✓] pay pharmacies and
10 pharmacists the appropriate rebate amount for each prescription drug that the
11 pharmacy or pharmacist sells to a person who has a card issued under sub. (3).[✓]

12 (b) The department may limit payment under par. (a)[✓] to claims that pharmacies
13 or pharmacists submit directly to the department^⓪

14 (c) The department may not impose transaction charges on pharmacies or
15 pharmacists that submit claims or receive payments under par. (a).[✓]

16 (d) 1. If a discrepancy exists between a rebate amount claimed by a pharmacy
17 or pharmacist under par. (a)[✓] and the amount paid by a manufacturer or labeler, the
18 party claiming a loss as a result of the discrepancy may hire an independent auditor
19 who is agreed on by the parties to review the discrepancy. If the discrepancy is not
20 resolved by the audit, the party advantaged by the discrepancy shall justify the
21 reason for the discrepancy or pay the amount necessary to resolve the discrepancy.

22 2. If the controversy continues after the procedures under subd. 1.[✓] have been
23 carried out, the department or the manufacturer or labeler may request a hearing
24 before the division of hearing and appeals of the department of administration as a
25 contested case under ch. 227.[✓]

****NOTE: The claims dispute process under par. (d) is taken from 2001 AB⁸⁵⁷. Do you want to include the claims dispute process in this bill? If so, should it be expanded to apply to rebates paid under Medical Assistance, Badger Care, Senior Care, the Disease Aids programs, WisconsinCare, and HIRSP?

1 (e) Any patient-identifiable data, as defined in s. 153.50 (1) (b) 1. or 2. or as
2 specified in s. 153.50 (3) (b) 1. to 7., that is collected under par. (a) shall be treated
3 as a patient health care record for purposes of s. 146.82.

****NOTE: Should the bill require DHFS to negotiate with manufacturers to obtain both the rebate that is provided under Medical Assistance and a supplemental rebate, or should DHFS just negotiate for one rebate for drugs purchased under the proposed prescription drug assistance program?

****NOTE: Should this bill include the following provisions related to the prescription drug assistance program that are in 2001 AB⁸⁵⁷: 1) a requirement that DHFS monitor compliance of pharmacies and pharmacists and report to legislature on compliance; 2) a requirement that DHFS promulgate rules relating to prohibitions on fraud; and 3) penalties for committing fraud that is prohibited by the rules referred to in item number 2?

4 SECTION 8. 149.143 (1) (a) of the statutes is amended to read:

5 149.143 (1) (a) First from the moneys transferred to the fund from the
6 appropriation account under s. 20.435 (4) (af) and from the moneys appropriated for
7 the health insurance risk-sharing plan under s. 20.435 (4) (jx).

History: 1997 a. 27; 1999 a. 9, 165; 2001 a. 16, 109.

8 SECTION 9. 448.075 of the statutes is created to read:

9 448.075 **Preferred drug list compliance.** Upon the request of the
10 department of health and family services, the board shall investigate a practitioner,
11 as defined in s. 450.01 (17), to determine whether the practitioner routinely
12 prescribes prescription drugs that are not on the preferred drug list established
13 under s. 49.69 to beneficiaries of state-supported prescription drug programs, as
14 defined in s. 49.69 (1) (i) or to persons enrolled in the prescription drug assistance
15 program under s. 49.69 without medical justification. If the board determines that
16 a practitioner routinely prescribes drugs that are not on the preferred drug list

1 without medical justification, the board may assess a forfeiture of \$250 against the
2 practitioner.

****NOTE: I set the assessment at \$250 because that is the amount of the lowest fine
under s. 448.09. Should it be a different amount or should the bill allow a range? Any
forfeitures assessed under this section will go to the school fund.

3 **SECTION 10.** 450.02 (2) of the statutes is renumbered 450.02 (2) (intro.) and
4 amended to read:

5 450.02 (2) (intro.) The board shall ~~adopt rules defining~~ promulgate all of the
6 following rules, which apply to all applicants for licensure under s. 450.05:

7 (a) Defining the active practice of pharmacy. ~~The rules shall apply to all~~
8 ~~applicants for licensure under s. 450.05.~~

History: 1985 a. 146; 1987 a. 65; 1995 a. 448; 1997 a. 68; 1997 a. 237 s. 727m.

9 **SECTION 11.** 450.02 (2) (b) of the statutes is created to read:

10 450.02 (2) (b) Requiring disclosure by a pharmacist to a prescription drug
11 purchaser who has a card issued under s. 49.692 (3) of the amount of the discount
12 on the retail price of the prescription drug that is provided to the purchaser as a
13 result of the program under s. 49.692.

14 **SECTION 12.** 450.075 of the statutes is created to read:

15 **450.075 Manufacturer gift reporting.** (1) In this section:

16 (a) "Clinical trial" means any experiment in which a drug is administered to
17 a human subject in connection with a research study.

18 (b) "Health benefit plan" has the meaning given in s. 632.745 (11).

19 (c) "Hospital" means a facility approved as a hospital under s. 50.35.

20 (d) "Nursing home" has the meaning given in s. 50.01 (3).

21 (2) (a) Except as provided in par. (c), each manufacturer shall annually report
22 to the board the value, nature, and purpose of any gift, payment, subsidy, or other
23 economic benefit valued at \$25 or more that the manufacturer directly or indirectly

1 provides to any of the following in connection with the manufacturer's promotional
2 or marketing activities:

- 3 1. A practitioner.
- 4 2. A pharmacist or an owner or operator of a pharmacy.
- 5 3. A hospital, nursing home, or organization that offers a health benefit plan,
6 or an employee of a hospital, nursing home, or organization that offers a health
7 benefit plan.
- 8 4. Any other person authorized to purchase prescription drugs for retail or
9 wholesale resale.

****NOTE: The Vermont bill requires manufacturers to report gifts to "any other person in Vermont authorized to prescribe, dispense, or purchase prescription drugs in this state." That provision presumably covers gifts to individual consumers. This bill does not require manufacturers to report gifts to individual consumers. Should it?

10 (b) A manufacturer shall ^{submit} the report required under par. (a) by January 1 of each
11 year for the 12-month period ending on the previous June 30.

12 (c) A manufacturer is not required to report any of the following under par. (a): ✓

- 13 1. A free sample of prescription drugs intended to be distributed to patients.
- 14 2. Payment of reasonable compensation or reimbursement of expenses in
15 connection with a clinical trial.
- 16 3. A scholarship or other support for a medical student, resident, or fellow to
17 attend an educational or policy-making conference sponsored by a professional
18 association, if the recipient of the scholarship or other support is selected by the
19 association.

****NOTE: If the intent of the reporting requirement is to learn who might be indebted to a pharmaceutical manufacturer, why allow these exceptions?

1 (3) Each manufacturer shall report to the board the name and address of the
2 person responsible for making reports under sub. (2) and shall notify the board of any
3 change in the information required under this subsection.

4 (4) A manufacturer who violates sub. (2) may be required to forfeit not more
5 than \$10,000 for each violation and, notwithstanding s. 814.04, to pay all actual costs
6 incurred by the state in prosecuting the violation, including reasonable attorney
7 fees.

8 (5) The board shall develop a form that manufacturers shall use to submit
9 reports under sub. (2).

10 (6) Any information reported by a manufacturer under this section that
11 constitutes a trade secret, as defined in s. 134.90 (1) (c), shall remain confidential.
12 The board may not release trade secret information obtained under this section,
13 except to the department of justice for the purpose of prosecuting a violation under
14 sub. (4). The form prescribed by the board under sub. (5) shall direct a manufacturer
15 to identify any information that is a trade secret.

16 (7) Annually, by March 1, the board shall submit to the legislature under s.
17 13.172 (2) and to the governor a report on disclosures made by manufacturers under
18 sub. (2).

****NOTE: What is the board supposed to report — whether manufacturers comply
with the reporting requirements or some summary of the gifts made?

19 SECTION 13. Nonstatutory provisions.

20 (1) ENROLLMENT FEE FOR PRESCRIPTION DRUG ASSISTANCE PROGRAM. The
21 enrollment fee for the prescription drug assistance program under section 49.692 (3)
22 of the statutes, as created by this act, shall be \$20, except that the department of
23 health and family services shall review the costs to administer the prescription drug

1 assistance program after it has been implemented for 12 months and shall reduce
2 the program enrollment fee if the earnings from the fee are greater than the costs
3 incurred by the department in administering the program.

4 **SECTION 14. Effective date.**

5 (1) This act takes effect on July 1, 2003, ^{on} the day after publication of the 2003-05
6 biennial budget act, or ^{on} the day after publication, whichever is later.

7 (END)

This act takes effect on the day after
publication on the 2nd day after publication
of the 2003-05 biennial budget act, or
on July 1, 2003, whichever is later. ©

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SECTION ~~h~~ 40.03 (6) (k) of the statutes is created to read:

40.03 (6) (k) Shall use the preferred drug list created under s. 46.69 (5) for group health insurance plans offered to state employees, except that for state employees covered by a collective bargaining agreement under subch. I or V of ch. 111 the board may use the preferred drug list only if permitted under the collective bargaining agreement.

49.69(5)